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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,722	02/07/2002	Andrew J.S. Evans	08565.136	3152
23483	7590	02/07/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			WIEKER, AMANDA FLYNN	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 02/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/071,722	Applicant(s) EVANS ET AL.	
	Examiner Amanda F. Wieker	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 January 2006 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 9, 15-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Great Britain Patent Specification Number 1,499,807 to Ring.

Regarding claims 1 and 19, Ring discloses an orthosis (see Figure 1) comprising an orthotic strut component (any of 2, 3, 5) for an orthosis comprising the combination of a ductile metallic tube (21) having a transverse cross-section of elongate shape (see Figure 2) and an internal core (22) of substantially uncured pre-impregnated fibre and plastics composite material within the tube (again, see Figure 2), the fibers of the core being substantially unidirectional and running lengthwise of the tube (page 2, lines 28-36; Ring defines the fibers as being "tows". See definition of "tow", which defines "a bundle of untwisted natural or man-made fibers").

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Ring discloses each and every structural element of the strut as set forth in claim 1. Ring discloses a tube having an internal core of pre-impregnated fibre and plastic composite material wherein the fibers are substantially unidirectional and run lengthwise of the sheet, but Ring is silent as to the method of making internal core. The claimed phrase “rolled-up, substantially uncured sheet” is being treated as a product by process limitation; that is, that the internal core is made by rolling up a sheet of material.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps (i.e., claim 1 implies the structural requirement that the fibers be unidirectional and run lengthwise in the tube, but does not require the internal core be a rolled-up sheet). Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Ring does not specify the claimed process used to make the plastic channels, it appears that the product in Ring would be the same or similar as that claimed; especially since both applicant’s product and the prior art product include an internal core of fibre and plastic composite, with substantially unidirectional fibers running lengthwise through the core.

Regarding claim 2, the tube is made of annealed aluminum alloy.

Regarding claims 3, 5 and 18, the cross-section of the tube is of an oblong-shape having substantially straight sides and rounded ends.

Regarding claims 4 and 5, the cross-sections of the strut and tube are substantially constant over the major part of the length of the strut component (see Figure 1 for example).

Regarding claim 9, after the strut is fitted to a user, the core is cured (lines 90-92).

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Regarding claim 16, the internal cross-sectional area of the tube is substantially fully occupied by the internal core (see Figure 2).

Regarding claim 20, Ring discloses that the struts can be shaped to fit the user (i.e., “bent”; see lines 84-86).

Ring discloses the invention substantially as claimed, however, Ring does not specify the dimensions of the strut.

At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art of orthotics to have provided the struts with the claimed length, wall thickness, internal circumference (and necessarily  $K$  value), cross-sectional ratio and thickness, because Applicant has not disclosed that such dimensions provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Ring’s orthotic struts, and Applicant’s invention, to perform equally well with either the dimensions shown by Ring or the claimed dimensions because both dimensions would perform the same function of securing to the lower leg of a user and providing support for the lower limbs. It would have been obvious to one skilled in the art of orthotics, at the time the invention was made, to have discovered the ideal dimensions of the struts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Therefore, it would have been prima facie obvious to modify Ring to obtain the invention as specified in claims 1-6, 9, 15-16 and 18-20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ring.

4. Claims 7, 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring in view of Japanese Patent Number 5-337966 ('966; in accordance with its English-language abstract).

Ring discloses the previously described orthosis and orthotic strut component, wherein the strut comprises an aluminum tube having a cross-section of elongate shape and an internal core of uncured plastics and fibre composite material. Ring does not specify an expansion agent within the plastics and fibre composite material.

'966 discloses a method of forming a plastics and fibre composite material into a desired shape. A plastic and fibre composite material is impregnated with an uncured hardenable resin and placed within a mold. '966 specifies that an inner kernel of a heat-activated expansion agent extends through the composite material, wherein the expansion agent is a foaming agent that includes an epoxy resin, to enlarge the composite material into the shape desired (i.e., by forcing the material into the shape of the mold).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis and orthotic strut disclosed by Ring, wherein an inner kernel of expansion agent is located within the plastic and fibre composite material, as taught by '966, to enlarge the composite material into the exact shape desired.

#### *Response to Arguments*

5. Applicant's arguments with respect to claims 1-9 and 15-20 have been considered but are moot in view of the newly presented ground(s) of rejection.

6. Applicant argues that Ring does not disclose an orthotic strut component having an internal core including a rolled-up sheet of pre-impregnated fibre and plastics composite material, wherein the fibers are unidirectional and run lengthwise of the tube.

The examiner disagrees. As noted above, this newly added limitation is considered to be a product-by-process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. In this case, claim 1 implies the structural requirement that the fibers be unidirectional and run lengthwise in the tube, but does not require the process step whereby the internal core is a rolled-up sheet.

Ring discloses the fibers to be “tows” of carbon fibers (line 33, page 2). As defined by the Oxford Online Dictionary (copy provided), a tow is considered to be a bundle of untwisted fibers. Based on a broad, reasonable interpretation of the term “tow”, Ring does in fact disclose the implied structural requirement that the fibers be unidirectional and run lengthwise in the tube. Ring does not disclose that the internal core be made by rolling up a sheet of uncured fibre and plastic composite material, however, this is not required because the limitation is a product-by-process limitation, which does not imply any structure to the claim over that which is met by Ring.

7. In addition, Applicant argues that the Easton reference does not teach or suggest the claim elements of claims 7, 8 and 17. Applicant's arguments are moot in view of the newly presented ground(s) of rejection.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

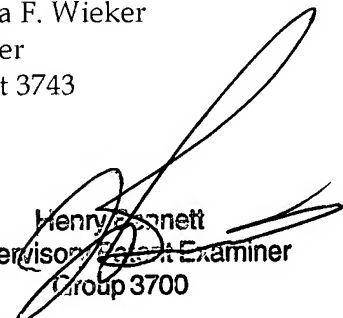
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
afw

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